

Batch 55

Box 19

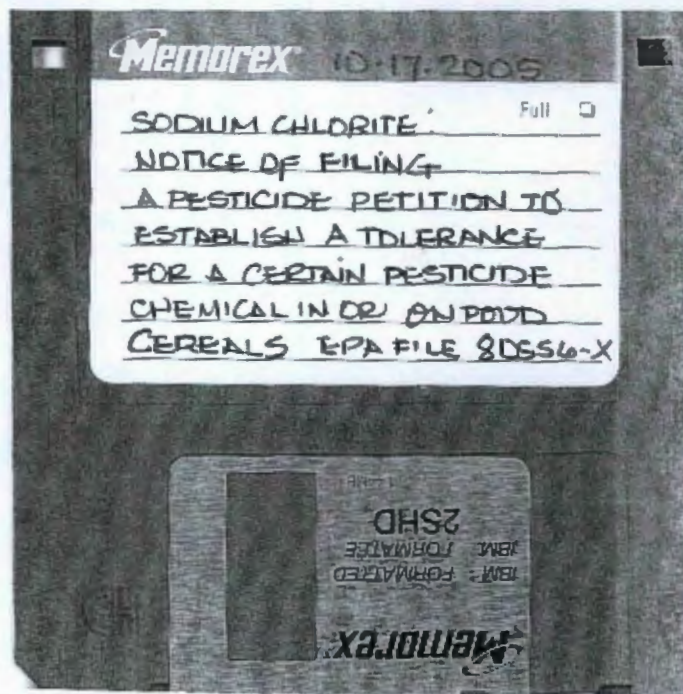
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9-8-06

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Electronic copy:  
Notice of Filing for Sodium  
Chlorite on Cereals

**Sodium Chlorite; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical In or on Food**

[Federal Register: \_\_\_\_\_, 2005 (Volume \_\_, Number \_\_\_\_)]  
[Notices]  
[Page \_\_\_\_-\_\_\_\_]  
From the Federal Register Online via GPO Access [wais.access.gpo.gov]  
[DOCID:fr\_\_\_\_y05-\_\_\_\_]

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ENVIRONMENTAL PROTECTION AGENCY  
[OPP-200\_-\_\_\_\_; FRL-\_\_\_\_-\_\_]

Sodium chlorite; Notice of Filing a Pesticide Petition to  
Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).  
ACTION: Notice.

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SUMMARY: This notice announces the initial filing of a pesticide  
petition proposing the establishment of regulations for residues of a  
certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP-  
2005-0207, must be received on or before \_\_\_\_\_, 200\_\_.

ADDRESSES: Comments may be submitted electronically, by mail, or  
through hand delivery/courier. Follow the detailed instructions as  
provided in Unit I. of the SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: \_\_\_\_\_, Registration Division  
(7505C), Office of Pesticide Programs, Environmental Protection Agency,  
1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone  
number: (703) 305-\_\_\_\_; e-mail address: \_\_\_\_\_.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an  
agricultural producer, food manufacturer, or pesticide manufacturer.  
Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides  
a guide for readers regarding entities likely to be affected by this  
action. Other types of entities not listed in this unit could also be  
affected. The North American Industrial Classification System (NAICS)



codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Copies of this Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under docket ID number OPP-2005-0207. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. Electronic access. You may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's

electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

#### C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ``late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. Electronically. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. EPA Dockets. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select ``search,'' and then key in docket ID number OPP-2005-0207. The system is an ``anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. E-mail. Comments may be sent by e-mail to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention: Docket ID Number OPP-2005-0207. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ``anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. Disk or CD ROM. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These



electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. By mail. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2005-0207.

3. By hand delivery or courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP-2005-0207. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

#### D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under FOR FURTHER INFORMATION CONTACT.

#### E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

#### II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain

pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

[[Page \_\_\_\_]]

Dated: \_\_\_\_, 200\_\_.

\_\_\_\_\_, Registration Division, Office of Pesticide Programs.

#### Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Bi-oxide Crop Science LLC

PP \_\_\_\_

EPA has received a pesticide petition (\_\_\_\_) from Bi-oxide Crop Science LLC, 401 South Wall Street, Suite 103, Calhoun, Georgia 30703 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for residues of sodium chlorite/chlorine dioxide in or on the raw agricultural commodities wheat, barely, oats, grain, straw, and aspirated grain fractions (wheat). Bi-oxide Crop Science LLC is seeking to obtain a Formulator's Exemption of Vulcan Chemical Technical Sodium Chlorite Solution 31.25 (25% active ingredient chlorite) EPA Reg. No. 5382-43 and in doing so will expand the use of sodium chlorite on field crops. Consequently Bi-oxide Crop Science LLC relies on Vulcan Chemical for supporting data. Vulcan Chemical is a member of the Chlorine Dioxide Panel of the Chemical Manufacturers Association (CMA) of Arlington, VA. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

#### A. Residue Chemistry



1. Plant metabolism. The metabolism of sodium chlorite and chlorine dioxide in plants is adequately understood for the purposes of establishing an exemption from the requirement of a tolerance. Sodium chlorite will convert to chlorine dioxide under acidic conditions. Chlorine dioxide is a powerful oxidizing agent that will oxidize phenol, amine, and organosulfur groups and in turn will be reduced to the terminal residue, chloride.

2. Analytical method. Chlorite residues can be determined by using ion chromatography with a sodium borate/gluconate mobile phase and a UV detector as described by Tsai et al. (*J Food Science*, 2001, 66:472-477). The method cannot discriminate between chlorite and chlorate and the limit of detection is 0.1ppm based on a signal-to-noise ratio of 3.

3. Magnitude of residues. Bi-oxide Crop Science LLC requests a data waiver for plant magnitude of residues. This request is based on the chemistry of sodium chlorite and chlorine dioxide. Both of these molecules are oxidizing agents. Chlorine dioxide is a reactive gas that when in contact with organic reducing agents such as phenol, amine, and organosulfur functional groups will be reduced to chloride. When chlorite is acidified, it is converted to chlorine dioxide and then consequently be reduced to chloride.

#### B. Toxicological Profile

1. Acute toxicity. The Bi-oxide Crop Sciences LLC 25% sodium chlorite solution will rely on data developed by Vulcan Chemical for the 80% technical sodium chlorite. The oral LD<sub>50</sub> values range from 255 to 270 mg/kg from male and female rats. The acute dermal toxicity LD<sub>50</sub> values range from 129 to 140 for male and female rates. Primary dermal toxicity found severe necrosis that persisted for up to 14 days after dosage for 4 out of 6 test animals. Primary eye irritation and dermal irritation were waived due to product corrosivity.

2. Genotoxicity. Bi-oxide Crop Science LLC has not generated new mutagenicity studies in support of sodium chlorite but instead is relying on those studies that support the Vulcan product. EPA, in the Integrated Risk Assessment System (IRIS) for chlorite (sodium salt) (CASRN 7758-19-2), assessed the genotoxicity of sodium chlorite. The following was listed in IRIS. Chlorite was assessed for genotoxicity in a number of *in vitro* and *in vivo* assays. Chlorite induced reverse mutations in *Salmonella typhimurium* (with activation) and chromosome aberrations in Chinese hamster fibroblast (Ishidate et al., 1984, *Food Chem Toxicol.* 22:623-636). In general the *in vivo* results were negative. In a micronucleus assay, negative results were found in ddY mice following an oral gavage (Hayashi et al., 1988, *Food Chem. Toxicol.* 26:487-500) and in Swiss CD-1 mice as treated by gavage for 5 days at 0, 8, 20, or 40 mg/kg/day (Meier et al., 1995, *Environ. Mutagen* 7:201-211). Meier also reported negative results in the sperm head abnormality assay in B6CC3F1 mice and in the bone marrow chromosomal aberration assay in Swiss CD-1 mice. Positive results were reported for a micronucleus assay of ddY mice when chlorite was administered by intraperitoneal injection (Hayashi, 1988).

3. Reproductive and developmental neurotoxicity. The Chlorine Dioxide Panel produced a rat two generation reproduction and development neurotoxicity report as was reported by Gill et al. (*J. Appl. Toxicol.* 2000, 20:291-303). F0 and F1 rats were allowed free

access to drinking water containing 0, 35, 70, or 300 ppm sodium chlorite for a 10-week prebreed period, for males and through mating, gestation, and lactation for females. The drinking water concentrations were approximately 4, 8, and 30 mg/kg/day for males and 5, 10, and 39 mg/kg/day for females. The intake of sodium chlorite resulted in a decrease in water consumption in all groups and a decrease in food consumption and body weights in the 70 and 300 ppm groups. There was no evidence of reproductive toxicity. Pup body weight decreased in the 300 ppm group. Changes in the nervous system were limited to small decrease in the auditory startle response in pups in the 70 and 300 ppm groups and there was a small decrease in absolute brain weight in pups the 300 ppm group. The no-observed-effect level (NOEL) for effects on reproduction and thyroid hormones was 300 ppm. The no-observed-adverse-level (NOAEL) for neurotoxicity was 300 ppm. Development toxicity of sodium chlorite in rabbit was reported by Harrington et al. (*J. Am. Coll. Toxicol.* 1995, 14:108-118). Mated New Zealand female rabbits received 0, 200, 600, or 1,200 ppm sodium chlorite in drinking water from day 7 to day 19 of pregnancy. Maternal food and water consumption decreased at 600 and 1,200 ppm, there were no treatment-related maternal abnormalities. There were no treatment related fetal structural abnormalities. The maternal and fetal NOEL was 200 ppm. Sodium chlorite is not considered to be a teratogenic or a selective development toxicant.

4. Subchronic toxicity. A 13-week rat feeding study was reported by Harrington et al. (*J. Am. Coll. Toxicology.* 1995, 14:21-33). Rats were daily gavaged with doses of sodium chlorite at 0, 10, or 80 mg/kg/day. At the 80 mg/kg/day dose there were several treatment-related deaths and morphological changes in the blood chemistry. Mean erythrocyte counts were decreased in both sexes. Splenic extramedullary hemopoiesis was observed in some animals at the 80 mg/kg/day dose. At the 25 mg/kg/day dose methemoglobin was increased in males. No adverse toxicological effects (NOAEL) were observed at the 10 mg/kg/day dose.

5. Chronic toxicity. The EPA Integrated Risk Information System (IRIS) reviewed the chronic toxicity of sodium chlorite. The review (EPA, 1986) stated that chlorite is classified as Group D; not classifiable as to human carcinogenicity. Under the draft Carcinogen Assessment Guidelines (EPA, 1996), the human carcinogenicity of chlorite cannot be determined because of a lack of human data and limitations in animals studies. Kurokawa et al. (*Environ. Health Perspect.* 1986, 69:221-235) conducted chronic oral studies with rats and found no evidence of carcinogenic activity from chlorite. Kurokawa's study has limited use since it involved an 85 week exposure period and the test animals had a high incidence of Sendai viral infection. Mouse studies by Kurokawa et al. and Yokose et al. (*Environ Health Perspect.* 1987, 76:205-210) showed an increase in liver and lung tumors in treated male mice; however the short exposure duration and high incidence of early mortality in the concurrent males from excessive fighting made statistical comparisons between concurrent controls and treated animals difficult to interpret. No increases in tumor incidence were seen in female mice. Chlorite induced skin tumors following initiation by DMBA, but the increase was not statistically significant. Chlorite has shown both positive and negative results in *in vitro* and *in vivo* genotoxicity studies.



6. Animal metabolism. The nature of chlorine dioxide and sodium chlorite residue in animals is adequately understood. Chlorine dioxide is rapidly reduced to form chloride. Sodium chlorite, while under acidic conditions in the digestive tract will convert to chlorine dioxide, which in turn will be reduced to chloride. Chloride will be eliminated by urinary routes.

7. Metabolite toxicology. The terminal metabolite is chloride.

8. Endocrine disruption. Sodium chlorite and chlorine dioxide are oxidizing agents, which in the presence of organic reducing groups will be reduced to the terminal residue, chloride. There were no indications of effects on fetal developmental in either rats or rabbits. At doses likely to be encountered from a field use of sodium chlorite, is not likely that either sodium chlorite or chlorine dioxide are endocrine disruptors.

#### C. Aggregate Exposure

1. Dietary exposure. The chronic reference dose (cRfD) and the acute reference dose (aRfD) were determined as 0.3 mg/kg/day and 2.5 mg/kg/day, respectively. These were based on the two generation rat NOAEL of 30 mg/kg/day and the acute oral LD<sub>50</sub> of 255 mg/kg/day and an uncertainty factor of 100. These reference doses were calculated based on EPA regulations concerning chlorite residue in drinking water since chlorine dioxide is used in water treatment for sanitation purposes.

i. Food. No residue of chlorite is expected in or on wheat, barley or oat raw agricultural commodities following the labeled use pattern and following standard agronomic practices. Chlorite is expected to convert to chlorine dioxide, which in turn will be reduced to the terminal residue, chloride. Sodium chlorite is exempt from the requirement of a tolerance when used in growing of the raw agricultural commodities crop group Brassica (cole) leafy vegetables and radishes (40 CFR §180.1070). EPA (Brennis, Antimicrobial Division, August 5, 2003) approved the post-harvest use of chlorine dioxide, as generated from sodium chlorite solution on stored potatoes at use rates of up to 400 ppm. EPA determined that it was unlikely that there would be a residue on the treated potatoes so no food tolerance was required. The U.S. Food and Drug Administration (FDA) approved the use of chlorine dioxide on cereal flour (including wheat and barley [malted flour]) in an unspecified quantity not more than sufficient for bleaching purposes (21 CFR §187.105). FDA approved the use of acidified sodium chlorite for use on poultry carcasses, red meat, sea food, and fruits and vegetables following a potable water rinse as a secondary direct food additive (21 CFR §173.325). Sodium chlorite and chlorine dioxide are also used in the manufacturing of paper and paper board for use in contact with food (21 CFR §186.1750).

ii. Drinking water. EPA established a maximum concentration limit (MCL) of chlorite in drinking water of 1.0 mg/L or 1 ppm. Chlorine dioxide is used to treat municipal drinking water supplies. The EPA FIRST model (FQPA Index Reservoir Screening Tool) was used to determine a conservative estimate of how much chlorite would move from a 427 acre watershed to a 13 acre 9 ft deep pond. The estimate considered 50% of the applied material of a total of 0.2 lb ai/acre as being in the chlorite form and further considered 8% of this moving to the pond and that all material would be in an ionic solution form and not adsorbed to sediment. The total calculated residue is 10 ppb of chlorite. The estimated amount of chlorite that would be in solution is approximately 100 times less than that of the established MCL.

2. Non-dietary exposure. Sodium chlorite and chlorine dioxide are currently not registered for use on any residential non-food site. Therefore, residential exposure to sodium chlorite and chlorine dioxide residues would be only through dietary exposure, including drinking water.

#### D. Cumulative Effects

There is no information currently available to indicate that toxic effects produced by sodium chlorite and chlorine dioxide are cumulative with those of any other compound.

#### E. Safety Determination

1. U.S. population. Based on the conservative exposure assumptions described above and on the completeness of the toxicology database, it can be concluded that total aggregate exposure from food and water to the U.S. population and all evaluated population subgroups from sodium chlorite from all proposed uses will be well below the chronic and acute RfDs. EPA generally has no concerns for estimated exposures below 100% of the RfD, since the RfD represents the level at or below which daily aggregate exposure will not pose an appreciable risk to human health. Thus, Bi-oxide Crop Sciences LLC believes it can be concluded that there is reasonable certainty that no harm will result from aggregate exposure to sodium chlorite residues.

2. Infants and children. In assessing the potential for additional sensitivity of infants and children to residues of sodium chlorite, the data from developmental toxicity studies in both the rat and rabbit and a two generation reproduction study in rats have been considered. The developmental toxicity studies evaluate potential adverse effects on the developing animal resulting from pesticide exposure to the mother during prenatal development. The reproduction study evaluates effects from exposure to the pesticide on the reproductive capability of mating animals through two generations, as well as any observed systemic toxicity. Since none of the studies indicate the offspring to be more sensitive and all effects were secondary to severe for maternal toxicity, Bi-oxide Crop Sciences LLC believes that infants and children are protected and that an additional uncertainty factor for infants and children is not warranted.

#### F. International Tolerances

No CODEX maximum residue levels (MRL's) have been established for residues of chlorine dioxide or chlorite on any crops at this time.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

January 3, 2006

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-361613  
EPA File Symbol or Registration Number: 5F6999  
EPA Receipt Date: 18-Oct-2005  
EPA Company Number: 80556  
Company Name: BI-OXIDE TECHNOLOGY, INC.

HEATH THOMASON  
BI-OXIDE TECHNOLOGY, INC.  
PO Box 2232  
CALHOUN, GA 30703-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee - **Revised**

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

**The Action previously identified as R18.0 has been reclassified as Action Code: R17.0**

NEW USE; EACH ADDITIONAL NEW FOOD USE; NO FEE; LINKED TO A PRIA APPLICATION;

**Please note that no fee is due for this action.**

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,

A handwritten signature in black ink, appearing to be "J. K. ...".

Front End Processing Staff  
Information Technology & Resources Management Division

Documentation of Discretionary Decisions

12/5/05 (62)

**Fee Category/ Issue (if not directly related to a specific category):**

EPA Reg No. 80556-R (sodium chlorite); associated with 5F6999; Should we change the existing R18.3 to a R17.3? ---- PM 22 Tony Kish

**Issue (describe in detail):**

The new fungicide outdoor food use on barley, wheat and oats was given a R18.3 with the thought that it might qualify for reduced risk status. However, the application did not claim or contain any reduced risk rationale. Furthermore, sodium chlorite was never treated as reduced risk in AD where most of the food uses reside (eg., fruit/vegetable wash water microbiological control, potable water treatment, hard food contact surface disinfection, etc). Therefore, changing it to an R17.3 is more appropriate. The R17.3 has a 22 month turnaround which is only two months more than the R18.3 of 20 months. Both PRIA codes have the same fee. Note that the only existing RD tolerance exemption is under 180.1070 for seed treatment.

**Decision (describe):**

RD agrees to change this additional new food from a R18.3 to a R17.3.

**Rationale (describe; include why this decision was not the same as any other closely related ones and reference those decisions):**

This PRIA code change is warranted because a reduced risk rationale was not submitted or claimed, and the AI was never treated as reduced risk in AD where the vast majority of food uses reside.

**Other Comments:**

\* Confirm no claims for RR made



**Petition for the Exemption from the Requirement of a Residue Tolerance for  
Sodium Chlorite / Chlorine Dioxide on Field Grown Wheat, Barley, and Oats.**

Submitted by:  
Bi-Oxide Crop Science, LLC.  
104 S Wall St., Suite 103  
Calhoun, Georgia 30703

Prepared by:  
Bruce Riggle, Ph.D.  
ChemReg International, LLC.  
710 11<sup>th</sup> Avenue, Suite E-301  
Greeley, Colorado 80631-6404



**A. Name, chemical identity, and composition of the pesticide chemical.**

Bi-oxide Crop Science, LLC (Bi-oxide) is submitting a petition for the exemption from the requirement of tolerance for the active ingredient sodium chlorite (CAS # 7758-19-2) / chlorine dioxide (CAS # 10049-04-4) on wheat, barley, and oats. Bi-oxide is seeking a formulator exemption registration and the product will be a repacking of the Vulcan Chemical 5382-43 registration. The formulation will contain 25% of sodium chlorite in a solution. The product will be named Biox Plus.

*ChemReg International LLC*

Tolerance Petition for Sodium Chlorite/Chlorine Dioxide on Small Grain Cereals

August 12, 2005

Page 2 of 10



**B. The amount, frequency, and time of application of the pesticide chemical.**

The proposed use pattern will involve one (1) to two (2) applications per season at a seasonal maximum rate of 0.16 to 2.0 lb active ingredient (ai) per acre to field grown wheat, barley, and oats and will be applied at and following the flowering growth stage. The expected post harvest interval (PHI) will be a minimum of three (3) weeks after the last application.

**C. Full reports of investigations made with respect to the safety of the pesticide chemical.**

Bi-oxide is requesting a Formulator's Exemption registration and is citing available data that supports the Vulcan Chemicals Technical Sodium Chlorite Solution 31.25, EPA Reg. No. 5382-43. Vulcan Chemicals is a member of the Chlorine Dioxide Panel that is administrated by the Chemical Manufacturers Association (CMA) of Arlington, VA. Vulcan Chemicals will provide Bi-oxide with all necessary support as is required with respect to mammalian and mutagenicity toxicity data.

In a 2000 toxicology review, the U.S. Environmental Protection Agency (EPA) identified chloride as the major urinary "metabolite" following intake of sodium chlorite and chlorine dioxide.

A CMA rabbit teratology study, as reported by Harrington et al (*J. Am. Coll. Toxicol.* 1995, 14:108-118), found the following. Mated female New Zealand white rabbits received 0, 200, 600, or 1,200 ppm of sodium chlorite in the drinking water from Day 7 to Day 19 of pregnancy. The maternal NOEL was 200 ppm (13.0 mg/kg/day) and body weight gains were significantly reduced at 1,200 ppm. The development NOEL was 200 ppm and there were small but statistically insignificant reductions in fetal body weight at 600 ppm and there were no treatment related fetal structural abnormalities.

A CMA 13 week (90 day) sub-chronic rat oral toxicity study, as reported by Harrington et al (*J. Am. Coll. Toxicol.*, 1995, 14:21-33.) found the following. Sodium chlorite was administered daily by gavage at doses of 0, 10, 25, or 80 mg/kg/day. Animals dosed at 25 mg/kg/day experienced ulceration, hyperkeratosis, and chronic inflation of stomach epithelium. At the 80 mg/kg/day level there were treatment related deaths and changes in erythrocytes. Splenic extramedullary hemopoiesis was also observed in some animals at 80 mg/kg/day level. The sub-chronic NOEL was 10 mg/kg/day.

A CMA two-generation reproduction and development neurotoxicity study with sodium chlorite in rat, as was reported by Gill et al (*J. Applied Toxicol.*, 2000, 20:291-303) found the following. The NOEL for effects on reproduction and thyroid hormone was 300 ppm. The NOAEL levels for hematological toxicity and neurotoxicity effects were 70 and 300 ppm, respectively. There was no evidence of reproductive toxicity.

EPA placed chlorine dioxide in the Group D category, not classifiable as a human carcinogen. Both positive and negative results have been reported for genotoxicity tests; as an oxidizer, chlorine dioxide would not target a specific molecular site but instead would oxidize aromatic amino acids, primary and secondary amine groups, and organic sulfur groups such as the amino acids methionine and cysteine.

*ChemReg International LLC*

Tolerance Petition for Sodium Chlorite/Chlorine Dioxide on Small Grain Cereals

August 12, 2005

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The Vulcan Chemical 80% technical sodium chlorite is a Category I material. The oral LD<sub>50</sub> values for male and female rats are 255 and 270 mg/kg, respectively. Acute dermal toxicity LD<sub>50</sub> values for male and female rats are 140 and 129 mg/kg, respectively. The primary dermal irritation testing found 4 out of 6 test animals had severe necrosis that persisted for up to 14 days after the dosage. Primary eye irritation and dermal sensitization studies were waived due to product corrosivity.

**D. The results of tests on the amount of residue remaining, including a description of the analytical method used.**

No field residue studies were done for acid activated sodium chlorite on wheat, barley, and/or oats. Bi-oxide had been informed that the Registration Division (RD) will accept published literature that shows sodium chlorite / chlorine dioxide will not result in residues of concern on raw agricultural commodities. Its position was taken since the chemistry is well known within the Agency.

A potato storage residue study by Tsai et al (*J Food Sci.*, 2001, 66:472-477) reported the following. Potatoes were treated in chambers for up to one hour with 1,000 ppm chlorine dioxide using a treated air stream and with 400 ppm chlorine dioxide using an atomizing spray system. Treated potatoes were peeled and extracted for residues. Residues were measured using ion chromatography with a sodium borate / gluconate mobile phase and a UV detector. Chlorine dioxide residue was measured as chlorite; the method could not discriminate between chlorite and chlorate as both eluted at the same time; the limit of detection for both chlorite and chlorate was 0.1 ppm based on a signal-to-noise ratio of 3. On a dry weight basis, chlorite residues on potato skin and whole potatoes were <0.6 ppm and <0.07 ppm, respectively. Chlorate residue on whole potato was <0.07 ppm. No residue analysis was done for processed potato; however, processing would be expected to reduce any potential remaining chlorite to chloride.

A strawberry residue storage study by Han et al (*J Food Protection*, 2004, 67:2450-2455) reported the following. Strawberries were treated with chlorine dioxide for 10 minutes at 3.0 mg/liter and then stored for one week at 4°C. Residues were determined using an amperometric titration method. For the day zero treatment, the chlorine dioxide and chlorite residues were  $0.19 \pm 0.33$  ppm and  $1.17 \pm 2.02$  ppm, respectively and at one week after treatment the chlorine dioxide and chlorite residues were none detectable and  $0.07 \pm 0.12$  ppm, respectively. This rapid loss of chlorite in one week represented a 94% reduction of the total that had been measured on day zero. This loss demonstrates the reactive and unstable nature of this chemistry in the presence of organic material.

Although there is no published literature to report on chlorine dioxide and chlorite treatments for field grown small cereal crops, chlorite has been reported to remove lignin from small cereal fractions. The lignin content in cereal grains can vary from 7 to 18%, depending upon the age of the plant; this lignin could serve as a sufficient reduction sink for any foliar applied chlorine dioxide/chlorite.

Based on the potato and strawberry results and with a minimum 3 week PHI for the labeled use on small cereals, measurable residues of chlorine dioxide and chlorite would not be expected in or on the grain or straw of field treated wheat, barley, and oats. Furthermore, residues would not be expected in poultry, swine, and/or cattle (beef and dairy) when livestock are fed with treated grain and/or straw (cattle feed only). Any chlorite residue that did remain on grain or straw (cattle feed only) would be expected to

*ChemReg International LLC*

Tolerance Petition for Sodium Chlorite/Chlorine Dioxide on Small Grain Cereals

August 12, 2005

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be reduced to chloride when under the acidic conditions as would typically be found in the digestive tracts of livestock. Specifically, when ruminant livestock were fed chlorate, there was a significant reduction in *Escherichia coli* numbers. The bacteria in the rumen reduced the chlorate to chlorite by way of nitrate reductase and then the chlorite was converted to the reactive chlorine dioxide form, which in turn oxidized and then killed the bacteria. The chlorine dioxide by-product following the oxidation/reduction process is chloride

Finally, because the degradation pathway is a chemical one, any collected samples that are stored under frozen conditions would still undergo the oxidation/reduction process, irrespective of biological activity. This steady conversion of chlorite to chloride would essentially make a storage stability study irrelevant.

**E. Practicable methods for removing residue that exceeds any proposed tolerance.**

An exemption from the requirement of a tolerance(s) is proposed for wheat, barley and oat raw agricultural commodities as well as meat, meat by-products, milk, and eggs of livestock. If residues of chlorite/chlorine dioxide were present and were of concern, such residues would be reduced through the oxidation/reduction process to chloride within one or two weeks following the time of discovery. This process would occur since these materials would be in or on reducing rich matrices. In addition, cereal grains are typically milled, ground and/or processed and these processes would further expose any potential remaining chlorite residue to reducing functional groups.



**F. Proposed tolerances for the pesticide chemical if tolerances are proposed.**

It is proposed that acidified sodium chlorite be exempt from the requirement of a tolerance for all associated raw agricultural commodities when applied to field grown wheat, barley, and oats.

### **G. Reasonable grounds in support of the petition.**

In a pre-registration meeting with the Registration Division (RD) on November 16, 2004, Bi-Oxide Crop Science LLC (Bi-Oxide) requested an exemption from the requirement of a tolerance for the food/feed use of acidified sodium chlorite when used on field grown wheat, barley, and oats. RD found these requests acceptable since sodium chlorite/chlorine dioxide chemistry is well known in the Agency. Sodium chlorite and chlorine dioxide are oxidizing agents that will be reduced to chlorite when in the presence of organic reducing functional groups.

EPA and the U.S. Food and Drug Administration (FDA) have already taken actions regarding chlorine dioxide and chlorite residues. Sodium chlorite is exempt from the requirement of a tolerance when used as a seed-soak treatment in the growing of the raw agricultural commodities crop group *Brassica* (cole) leafy vegetable and radishes (40 CFR §180.1070). EPA (Antimicrobial Division, August 5, 2003) approved the post-harvest use of chlorine dioxide, as generated from sodium chlorite, on stored potatoes at rates of up to 400 ppm. EPA stated that "After careful evaluation by our scientific staff it was determined that it is unlikely there would be a residue of chlorine dioxide on the potatoes, so no food tolerance is required". No restrictions were placed on potato culls, which are a cattle feed item. FDA approved the use of chlorine dioxide on cereal flours (including wheat and barley [malted flour]) in an unspecified quantity not more than sufficient for bleaching purposes (21 CFR §137.105).

The use of acidified sodium chlorite as a fungicide for field grown wheat, barley, and oats with one or two application at or following flowering with a minimum 3 week PHI after the last application is not expected to result in any residues of concern. The terminal residue of sodium chlorite and chlorine dioxide is chloride.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

October 25, 2005

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

NO PAYMENT DUE WITH THIS ACTION

OPP Decision Number: **D-361613**  
EPA File Symbol or Registration Number: **5F6999**  
Product Name: Petition for Tolerance Exemption- Sodium Chlorite  
(Field Treated Wheat, Barley & Oats)  
EPA Receipt Date: 18-Oct-2005  
EPA Company Number: 80556  
Company Name: BI-OXIDE TECHNOLOGY, INC.

BRUCE RIGGLE  
BI-OXIDE TECHNOLOGY, INC.  
PO Box 2232  
CALHOUN, GA 30703-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: **A38.0**

NEW AI; FOOD USE; WITH EXEMPTION;  
NO FEE: LINKED TO A PRIA APPLICATION;

No Fee due with this action.

By USPS:  
USEPA Washington Finance Center  
Pesticide Registration Service Fee  
PO Box 360277  
Pittsburgh, PA 15251

By Courier:

U.S. EPA Washington Finance Center  
Pesticide Registration Service Fee  
C/O Mellon Client Service Center  
500 Ross Street, Room 670  
Box 360277  
Pittsburgh, PA 15251-6277  
Attn: EPA Module Supervisor  
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at [www.epa.gov/pesticides/fees](http://www.epa.gov/pesticides/fees).

Please send Registration Service Fee Waiver requests to:

By USPS:

Document Processing Desk (WAIVER)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave NW  
Washington, DC 20460

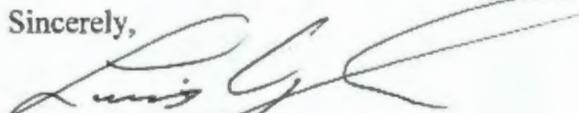
By Courier:

Document Processing Desk (WAIVER)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall #2  
1801 S. Bell St.  
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6432.

Sincerely,



Front End Processing Staff  
Information Technology & Resources Management Division



## Fee for Service



This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies?    ☐ Fee Waiver?  
☐ volpay    % Reduction: \_\_\_\_\_

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

Risk Mgr.

32

Receipt No.

S-

785523

EPA File Symbol/Reg. No.

5F6999

Pin-Punch Date:

10/18/05

☐ This item is NOT subject to FFS action.

### Action Code:

Requested:

Granted:

A38.0

Amount Due: \$ \_\_\_\_\_

### Parent/Child Decisions:

Reviewer: Henson

Date: 10-20-05

Remarks:



# Receipt for Tolerance Petition

S: 765523

Resubmission: ☐ Yes ☒ No

Regulatory Type: Tolerance Petition

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 80556 BI-OXIDE TECHNOLOGY, INC.

V

Risk Mgr: Antimicrobials Division, Risk Management Team 32

Petition #: SF6898 Fee Waived: ☐ Yes ☒ No Fee:

Petition Type: F - Raw Agricultural Commodity

Print Letter

Enter More Information

Tracking

Application Date: 13-Oct-2005

OPP Rec'd Date: 18-Oct-2005

Front End Date: 19-Oct-2005

Risk Manager Send Date: 24-Oct-2005

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Sodium Chlorite Use for Field treated Wheat, Barley, and Oats.  
10/24/05, A38.D [child of Reg. # 80556-R and D-361590] (LWW).

New Ingredient

Received Date:

Not a New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

# ChemReg<sup>®</sup>

INTERNATIONAL, LLC

710 ELEVENTH AVENUE, SUITE E-301  
GREELEY, COLORADO 80631

1990 OLD BRIDGE ROAD, SUITE 201  
LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 970-392-1445  
Fax: 970-392-1961  
Main: 703-492-0445

E-MAIL: [riggle@chemreg.com](mailto:riggle@chemreg.com)  
WEB SITES: [www.chemreg.com](http://www.chemreg.com)  
[www.pesticide.net](http://www.pesticide.net)

**BRUCE D. RIGGLE, PH.D.**

October 13, 2005

Via Hand Delivery

U.S. Environmental Protection Agency  
Office of Pesticide Programs (7404C - APPL. (REG FEE))  
Registration Division  
Crystal Mall #2  
1810 Bell Street  
Arlington, Virginia 22202  
Attention: Carl Grable

Ref: Sodium Chlorite Registration for Field Treated Wheat, Barley, and Oats.  
Formulator's Exemption / Repack of EPA Reg. No. 5382-43  
Petition for an Exemption from the Requirement of a Tolerance  
Reduced Risk Use Classification Request  
Proposed PRIA Fee Code: R18

Biox Plus EPA No. 80556-XXX

Dear Carl:

ChemReg International LLC (ChemReg) is submitting on behalf of Bi-oxide Crop Science (Bi-oxide) for a registration and an exemption from the requirement of a tolerance for the field use of sodium chlorite on wheat, barley, and oats. The retail product will be named Biox Plus. This follows the pre-registration meeting of November 16, 2004 with the Registration Division (RD) of the U.S. Environmental Protection Agency (EPA). In that meeting, ChemReg informed RD that Bi-oxide would supply the necessary data for a Formulator's Exemption Registration (a repack) for sodium chlorite and that Bi-oxide also wished to expand the existing use pattern for sodium chlorite to include field applications to wheat, barley, and oats and that the EPA accepted terminal residue is sodium chloride (table salt). Also in that meeting ChemReg requested that RD accept data waiver requests in place of actual GLP Guideline Studies. RD

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**CONSULTANTS TO SUCCESS<sup>®</sup>**

**Expertise in Toxicology, Residue and Product Chemistry, Environmental Fate, Efficacy, Registration Strategies and Implementation, Regulatory Compliance, Label Development, Exposure and Risk Assessments, Data Citation and Compensation, Study Design and Monitoring.**



agreed to this request based on the fact that the chemistry is well known within the Agency. RD did however stipulate that the waivers would have to be detailed and would have to address the basic requirements for field use as not covered in the current Vulcan Chemical registered use pattern. RD also agreed to ChemReg's request that the detailed waiver requests would be in a report format as specified in PR Notice 86-5 and would be assigned MRID numbers.

The Agency and the U.S. Food and Drug Administration (FDA) have already taken the following actions regarding crop and food uses of sodium chlorite and chlorine dioxide (the Agency accepts these two chemicals to be one and the same). Sodium chlorite is exempt from the requirement of a tolerance when used as a seed-soak treatment in the growing of the raw agricultural commodities crop group *Brassica* (cole) leafy vegetables and radishes (40 CFR §180.1070). The Agency (Brennis, Antimicrobial Division, August 5, 2003) approved the post-harvest use of chlorine dioxide, as generated from sodium chlorite, on stored potatoes at rates of up to 400 ppm. EPA exempted sodium chlorite and chlorine dioxide from the requirement of a tolerance and stated that "After careful evaluation by our scientific staff it was determined that it is unlikely that there would be a residue of chlorine dioxide on the potatoes, so no food tolerance is required". It should be noted that no restrictions were placed on potato culls from this post harvest use and that potato culls are a cattle-feed item. FDA approved the use of chlorine dioxide on cereal flours (including wheat and barley [malted flour]) in an unspecified quantity not more than sufficient for bleaching purposes (21 CFR §137.105). This approved use would potentially leave residues of sodium chlorite, how experience with this chemistry has demonstrated that in the presence of organic matter, chlorine dioxide will be rapidly reduced to sodium chloride.

Again, Bi-oxide is requesting a Formulator's Exemption registration and Bi-oxide will rely on Vulcan Chemical (EPA Reg. No. 5382-43) for product chemistry (40 CFR §158.190), wildlife and aquatic organisms data (40 CFR §158.490), and toxicology data (40 CFR §158.340). Included in this registration submission is a letter of support from Vulcan Chemicals. To support the other (minimum) data requirements, Bi-oxide has also included guideline data waiver requests (again in the 86-5 report format). These reports, with associated Guideline Reference Numbers are listed in Table 1.

Table 1. Reports submitted in support of a field use of sodium chlorite on wheat, barley, and oats.

Guideline Reference Number	Guideline Study Name (OPPTS No.)	MRID Number	Submitter	Status	Note
171-4	Magnitude of the Residue (OPPTS 860.1500)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request (1)
171-4	Nature of the Residue (OPPTS 860.1300)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
162-1	Soil Metabolism (OPPTS 835.3300)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
164-1	Soil Dissipation (OPPTS 835.6100)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
163-1	Sediment and Soil Adsorption/Desorption (OPPTS 835.1220)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
161-2	Photolysis (OPPTS 835.2210)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
161-1	Hydrolysis (OPPTS 835.2130)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
122-1	Nontarget Plant (OPPTS 850.4100)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
141-1; 141-2	Nontarget Pollinating Insects (OPPTS 850.3020; 3030; 3040)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
201-1; 202-1	Pesticide Drift Evaluation (OPPTS 840.1000)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request
132-1; 133-3, 133-4	Post-Application Exposure (OPPTS 875.2000)	To be assigned	Bi-oxide Crop Science LLC	Own	Detailed Waiver Request

(1) Residue Analytical Method (Guideline Reference No. 171-4) would not be required if tolerance requirement is waived.

ChemReg requests that RD classify the active ingredient sodium chlorite and its use pattern on field treated small grain cereals as a reduced risk pesticide. This request is based on the facts that the material is an oxidizer and that the terminal residue is sodium chloride (table salt). In addition, the Agency (Antimicrobial Division) has already allowed for its use as a post harvest treatment on stored potatoes. Again for these reasons ChemReg believes that the field use of sodium chlorite on small cereal grains should fall in the reduced risk category. A sodium



chlorite based product would fit well into a fungicide program on a crop such as spring wheat and could serve as a substitute for a number of the current strobilurin (examples: azoxystrobin and pyraclostrobin) and triazole (examples: tebuconazole and propiconazole) based fungicides. A seasonal rotation using Biox Plus would be very beneficial for that strobilurin class since the registrants and the manufacturers actively promote resistance management strategies that include using different chemistries with different mechanisms of action. The use of Biox Plus could also result in the overall reduction in the use and the resulting residues of these fungicides. In addition the field use of Biox Plus should pose no hazard to the environment and non-target plants and animals.

Under the Registration Division Fee Schedule (PRIA), ChemReg believes that the Bioxide registration request for the reduced risk use of sodium chlorite and for the request for an exemption from the requirement of a tolerance qualifies as EPA Number R18. An R18 has a decision time of 20 months as per the 2006 Federal Fiscal Year. Again it is noted that this would not be the first crop use; this is based on the previous regulatory decision by the Agency (Brennis, Antimicrobial Division, August 5, 2003) in which the post-harvest use of chlorine dioxide, as generated from sodium chlorite, was approved on stored potatoes at rates of up to 400 ppm. In that decision a food residue tolerance was waived. Once the Agency assigns a PRIA Fee Code, Bi-oxide will request a waiver and will submit all of the necessary paperwork.

Attached with this cover letter are the following:

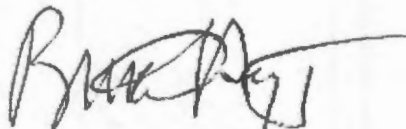
1. Agent authorization letter
2. Letter to EPA Summarizing the November 16, 2004 Pre-Registration Meeting
3. Copy of Pre-Registration Meeting Presentation
4. Application (EPA Form 8570-1)
5. CSF (basic)
6. Label (5 copies)
7. Transmittal Bibliography
8. Detailed Data Waiver (11) Reports (3 copies)
9. Executive Summary Report (3 copies)
10. Tolerance Petition (Exemption Request)
11. Letter of Authorization from Vulcan Chemicals
12. Notice of Filing for Federal Register
13. Computer disc containing copy of the Notice of Filing
14. Formulator's Exemption Statement (EPA Form 8570-27)



Office of Pesticide Progra  
Registration Division  
Carl Grable  
October 13, 2005  
Page 5 of 5

If you have any questions or need additional information, please contact me at (970) 392-1445 or (703) 927-8546 (cell phone).

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce D. Riggle", with a long horizontal line extending to the right.

Bruce D. Riggle, Ph.D.

Attachments

Volume 1 of 13 of Submission

**TRANSMITTAL DOCUMENT**

**NAME AND ADDRESS OF AGENT/SUBMITTER:**

ChemReg International, LLC  
Bruce D. Riggle, Ph.D.  
710 11<sup>th</sup> Avenue, Suite E-301  
Greeley, CO 80631-6404

**NAME AND ADDRESS OF REGISTRANT:**

Bi-oxide Crop Sciences LLC  
401 South Wall Street, Suite 103  
Calhoun, Georgia 30703

**REGULATORY ACTION:**

Submission of data waiver request reports to support a registration of Bi-oxide Crop Science LLC (Bi-oxide) 25% sodium chlorite end-use product for field use on wheat, barley, and oats and to support an exemption from the requirement of a tolerance for chlorite and chlorine dioxide on the appropriate raw agricultural commodities.

**TRANSMITTAL DATE:**

October 13, 2005

**LIST OF SUBMITTED REPORTS:**

<u>MRID</u> <u>NUMBER</u>	<u>VOLUME</u> <u>NUMBER</u>	<u>STUDY TITLE</u>	<u>EPA</u> <u>GUIDELINE NO.</u>
	1 of 13	TRANSMITTAL DOCUMENT	N/A
	2 of 13	Executive Summary Review of Sodium Chlorite/Chlorine Dioxide For Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-1; August 3, 2005; 11 pages.	N/A

3 of 13	Waiver Request for Magnitude of the Residue in Plants and Livestock Animals for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-2; June 21, 2005; 233 pages.	171-2,3,4
4 of 13	Waiver Request for Nature of the Residue in Plants for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-3; June 21, 2005; 116 pages.	171-4
5 of 13	Waiver Request for Soil Dissipation for the Evaluation of Sodium Chlorite /Chlorine Dioxide For Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-4; August 1, 2005; 87 pages.	164-1
6 of 13	Waiver Request for Photodegradation in Water for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-5; August 2, 2005; 108 pages.	161-2
7 of 13	Waiver Request for Hydrolysis for the Evaluation of Sodium Chlorite/ Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-6; August 2, 2005; 41 pages.	161-1
8 of 13	Waiver Request for Metabolism in Aerobic Soil for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-7; August 2, 2005; 95 pages.	162-1



9 of 13	Waiver Request for Sediment and Soil Adsorption/Desorption for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-8; August 1, 2005; 74 pages.	163-1
10 of 13	Waiver Request for Re-Entry Exposure Protection Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Wheat, Barley, and Oats; Report No. CRGC-2005-9; July 13, 2005; 55 pages.	132-1, 133-3,4
11 of 13	Waiver Request for Spray Drift for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-10; August 1, 2005; 76 pages.	201-1, 202-1
12 of 13	Waiver Request for Non-Target Terrestrial Plant Requirements for the Evaluation of Sodium Chlorite/Chlorine Dioxide for Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-11; July 19, 2005; 105 pages.	121-1, 122-1
13 of 13	Waiver Request for Non-Target Pollinating Insects and Honey Bees for the Evaluation of Sodium Chlorite/Chlorine Dioxide For Use on Field Grown Wheat, Barley, and Oats; Report No. CRGC-2005-12; July 19, 2005; 65 pages.	141-1, 141-2

COMPANY AGENT: Bruce D. Riggle  
NAME

Bruce D. Riggle  
SIGNATURE

Contact information: Bruce D. Riggle, Ph.D., phone 970-392-1445; cell 703-927-8546; riggle@chemreg.com.

**B. The amount, frequency, and time of application of the pesticide chemical.**

The proposed use pattern will involve one (1) to two (2) applications per season at a seasonal maximum rate of 0.16 to 2.0 lb active ingredient (ai) per acre to field grown wheat, barley, and oats and will be applied at and following the flowering growth stage. The expected post harvest interval (PHI) will be a minimum of three (3) weeks after the last application.

**F. Proposed tolerances for the pesticide chemical if tolerances are proposed.**

It is proposed that acidified sodium chlorite be exempt from the requirement of a tolerance for all associated raw agricultural commodities when applied to field grown wheat, barley, and oats.